REMARKS

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

The rejection of claims 1-10 under 35 U.S.C. §112(first paragraph) as for lack of written description is respectfully traversed.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the invention at the time the application was filed (Guidelines for the Examination of Patent Applications Under 35 USC 112, P1, Written Description Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001)("Written Description Guidelines"). Possession may be shown in a variety of ways including a description of distinguishing identifying characteristics sufficient to show that the applicant was in possession of the invention (Written Description Guidelines at 1104). An actual reduction to practice is not required (Id.). There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed (Written Description Guidelines at 1105). Rejection of an original claim is meant to be a rare occurrence (Id.) The limitations of claims 1 and 5, as presently claimed, were contained in the present application as filed. Accordingly, based on this presumption, there is an adequate written description of the claimed invention as filed.

Accordingly, the rejection of claims 1-10 for lack of written description is improper and should be withdrawn.

The rejection of claims 1-10 under 35 U.S.C. § 112 (first paragraph) for lack of enablement is respectfully traversed.

In order for claims to be enabled, the specification, when filed, must contain sufficient information as to enable one skilled in the art to make and use the claimed invention. (Manual of Patent Examining Procedure ("MPEP") 2164.01). As long as the specification discloses at least on method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, the enablement requirement is satisfied. (In re Fisher, 427 F.2d. 833, 839, 166 USPQ 18, 24 (CCPA 1970); MPEP 2164.01(b)). In determining whether a patent application is in compliance with the enablement requirement, the PTO will consider whether one of ordinary skill in the art could practice the invention without undue experimentation. In re Wands, 858 F.2d. 731, 8 USPQ2d 1400 (Fed. Cir. 1988)).

It is the position of the U.S. Patent and Trademark Office (PTO) (as stated on page 5 of the outstanding office action) that the present specification is not enabling for *in vivo* treatment because *in vitro* modeling systems do not correlate well with the *in vivo* environment. However, one skilled in the art is enabled to use antibodies in a method of treatment of HIV infection both *in vitro* and *in vivo*.

In particular, U.S. Patent No. 6,432,405 (copy attached hereto), which issued on August 13, 2002, relates to administering to a patient a anti-CD44 antibody to inhibit HIV infection. Thus, applicants submit that it was well within the skill of one of ordinary skill in the art (as of the filing date of the present application) to administer antibodies to treat HIV infection, either to cells *in vitro* or *in vivo*. Further, as evidence that *in vitro* modeling systems correlate well with the *in vivo* environment with respect to antibody treatment for HIV infection (as well as evidence that those skilled in the art could practice the claimed invention both *in vitro* and *in vivo*), Reimann et al., AIDS RES HUM

RETROVIRUSES, 13(11):933-43(1997)(abstract), Reimann et al. , AIDS RES HUM RETROVIRUSES, 18(11):747-55(2002)(abstract), Reimann et al. , AIDS RES HUM RETROVIRUSES, 11(4):517-25(1995)(abstract), Reimann et al. , AIDS RES HUM RETROVIRUSES, 9(3):199-207(1993)(abstract) and Boon et al., TOXICOLOGY, 172(3):191-203(2002)(abstract) (copies attached hereto) indicate that certain antibodies directed against CD4 could block HIV infection both *in vitro* and *in vivo*. These references show that the *in vitro* results were predictive of *in vivo* results using CD4 antibodies to block HIV infection. Thus, one skilled in the art would accept the *in vitro* model as correlating to *in vivo* success with respect to antibodies to treat HIV. Accordingly, one skilled in the art, with the knowledge contained in the present specification, could practice the present invention. In particular, one skilled in the art, without undue experimentation, could use the methods present in the present specification (page 9, line 23 to page 11, line 15), as well as the knowledge contained in the art to administer antibodies to block HIV infection *in vitro* and *in vivo*.

Further, it is the position of the PTO, as set out on pages 8-9 of the office action dated August 13, 2002, that the state of antibody treatment is unpredictable. Applicants respectfully disagree. As set forth in the references cited above, the studies demonstrated that administration of antibodies to treat HIV infection was feasible and supportable by the evidence as of the filing date of the present application. (See last line of Reimann et al., AIDS RES HUM RETROVIRUSES, 13(11):933-43(1997)(abstract)).

Further, the fact the experimentation, even if complex, is required does not make it undue, if the art typically engages in such experimentation (MPEP 2164.01).

Accordingly, the rejection is improper and should be withdrawn.

In view of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

November 14, 2003
Date

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